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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/009,023	04/12/2002	Ian L Brown	28053/37955	6243

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EXAMINER

MAIER, LEIGH C

ART UNIT PAPER NUMBER

1623

DATE MAILED: 06/09/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/009,023

Applicant(s)

BROWN ET AL.

Examiner

Leigh C. Maier

Art Unit

1623

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2005.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-38 is/are pending in the application.
- 4a) Of the above claim(s) 11-25 and 34-38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10 and 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on February 14, 2005 has been entered.

Claims 1, 3, 5-10, and 26-33 have been amended. Claims 1-38 are pending. Claims 11-25 and 34-38 have been withdrawn as being drawn to a non-elected invention. Claims 1-10 and 26-33 are under examination. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action. Any rejection or objection not expressly repeated has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-10 and 26-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1-10 are drawn to various methods comprising "replacing at least 10% of the individual's daily carbohydrate intake with amylase resistant starch." Claims 26-33 are drawn to

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various methods comprising “administering to the individual a composition comprising at least 10g of amylase resistant starch.” However, the disclosure does not specify the method by which the amount of amylase resistant starch is measured. See, for example Table 1 of “Megazyme Resistant Starch Assay Procedure.” (It is noted that the date of this reference does not qualify it as “art,” but it compares assays known at the time of the invention. See references at page 2.) The data show the variation in RS depending on the particular assay used. Furthermore, it appears that the results of a *given* assay may vary considerably. Compare the data discussed above with Table 2 of ASP et al (Nutr. Res. Rev., 1996). Furthermore, SEIB et al (US 5,855,946) describe different results in using different amylases. See Table V. The claims are thus rendered vague and indefinite.

Claim Rejections - 35 USC § 102

Claims 1-5, 7-10, 26-28, and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by BROWN et al (WO 96/08261).

BROWN discloses a composition amylase-resistant starch and unsaturated fat. See Table 9. From Table 3, it appears that the amylase-resistant starch content is at least 18.1%. All of the fat comes from an unsaturated source. The table discloses other starch fractions wherein the amount is increased. Assuming that this unmodified starch is used, the total amount of amylase-resistant starch in the Table 9 composition is about 90 g, which is about 11% of the total carbohydrate (starch + sucrose + wheat bran). In order to ingest 10 g of amylase-resistant starch per day, the daily intake of this composition would have to be about 113 g. The reference

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discloses feeding this composition to pigs, and one would expect that a pig would eat at least this much per day. Thus the methods are anticipated.

Claim Rejections - 35 USC § 103

Claims 6 and 29 are rejected under 35 U.S.C. 103(a) as being unpatentable over KLOR et al (US 5,886,037) in view of WIBERT et al (US 5,776,887) and further in view of SEIB et al (US 5,855,946).

KLOR teaches a composition for the treatment of obesity and diabetes. See col 2, lines 21-29 and example in col 5. The composition comprises 46 wt% carbohydrate, 20 wt% protein, and 29.6 wt% fat. The fat source appears to be essentially completely unsaturated. The reference suggests the use of a carbohydrate that gives small rise to plasma lipid or insulin levels and is slowly digestible. See col 4, lines 28-36. The reference does not exemplify the use of resistant starch.

WIBERT teaches the Novelose starch is a slowly absorbed resistant starch that has utility in the preparation of a variety of food products, including a nutritionally complete drink. See examples and col 3, lines 47-49.

SEIB teaches that Novelose comprises (depending on the method of measurement) at least 32.6% amylase-resistant starch. See Table V.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to prepare a composition according to the teaching of KLOR with a resistant starch, such as Novelose, because WIBERT had taught that it is a slowly absorbed carbohydrate and has utility in the preparation of food products. It would be further obvious to administer this

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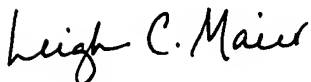
composition for the treatment of obesity with a reasonable expectation of success, because KLOR had taught this utility. A product prepared according to KLOR and administered in the amount of about 2000 kcal/day, would provide amylase-resistant starch and unsaturated fat in the required amounts.

Examiner's hours, phone & fax numbers

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh Maier whose telephone number is (571) 272-0656. The examiner can normally be reached on Tuesday, Thursday, and Friday 7:00 to 3:30 (ET).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. James O. Wilson (571) 272-0661, may be contacted. The fax number for Group 1600, Art Unit 1623 is (703) 872-9306.

Visit the U.S. PTO's site on the World Wide Web at <http://www.uspto.gov>. This site contains lots of valuable information including the latest PTO fees, downloadable forms, basic search capabilities and much more.



Leigh C. Maier
Primary Examiner
May 13, 2005